

## **REMARKS / ARGUMENTS**

Claims 1, 5-16 and 29-30 are pending and stand rejected. By the foregoing amendment, the applicants have amended claim 1. Claims 32-33 are canceled. Claims 34-35 are new, but first originally presented in the Amendment submitted on June 10, 2009. No new matter is added by the amendments. Support for the amendments are found in the specification as filed, for example on page 6, lines 25-27. Reconsideration and allowance are respectfully requested.

The applicants note the Examiner neither entered nor examined new claims 34-35 that were newly presented in the Amendment submitted on June 10, 2009. Claims 34 and 35 are product by process claims that should be examined with the product claims from which they depend. Therefore, the applicants submit the finality of the instant Office Action is premature, and request the Examiner withdraw the finality thereof.

On page 2 of the Office Action the Examiner maintained the rejection of claims 1, 5-16 and 29-30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The applicants have overcome the rejection by the foregoing amendment to claim 1. The entire range of amended claim 1, i.e., about 1.5% to 10%, is described in the specification, for example on page 6, lines 25-27, and complies with the written description requirement and is therefore allowable. Claims 5-16 and 29-30 which depend from amended claim 1 and recite additional features also comply with the written description requirement and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

On page 11 the Examiner maintained the rejection of claims 1, 5-16 and 29-30 under 35 U.S.C. § 103(a) as being unpatentable over Esperester et al. (WO 01/28363, the “’363 reference”) in view of Bilgrami et al. (1993) in view of Struengmann in view of Mathiowitz in view of Saslawski et al. in view of Abramovici et al. and in view of Lieberman, H., Ed. et al. (1990). The applicants respectfully traverse the rejection. The Examiner did not find persuasive the previously-submitted declaration (September 25, 2008). The applicants disagree and provide the following further explanation.

As noted by the applicants in the previously submitted Response, superior stability occurred in the applicant’s tablets where the colloidal, anhydrous silica was added to the red vine leaf extract during the spray drying process. Adding colloidal anhydrous silica **during** the step

of drying of the red vine leaf extract gave from 2 to 4-5X better stability. As is noted in further detail below, the stability characteristics referred to in the declaration are different than those discussed by the Examiner with respect to Chang. When viewed in the proper context, the claimed tablets are unexpectedly superior over any tablet that could be made by a process according to the combination of the references.

The Examiner alleges the submitted data does not provide evidence of an unexpected result in light of the disclosure of the newly cited Chang et al. reference (i.e., that adding anhydrous silica enhances tablet stability). The Examiner pointed to the improved flow characteristics, reduced tablet thickness and improved tablet hardness resulting from the addition of colloidal silica in Chang to show that “the addition of 35mg of colloidal anhydrous silica to red vine leaf provides for better stability which is expected” (pages 26-27 of the Office Action). However, these characteristics of Chang are not the characteristics in which the unexpected stability properties of applicant’s tablets are reflected. The applicant’s tablets showed unexpectedly superior storage stability characteristics. The characteristics reflected in Chang are unrelated to, and not predictive of, the storage stability of the applicant’s tablets. Chang teaches the use of silica for enhancing the crushing stability, i.e., stability against physical impact. In the applicant’s tablets, silica is used to enhance the disintegration stability, i.e., stability against moisture, air and temperature. Such stabilities are not interrelated and thus one skilled in the art viewing Chang would not contemplate the use of silica for anything other than enhancing crushing stability, let alone for improving storage stability.

On page 27 of the Office Action the Examiner continued to allege that the tablets in the declaration are too different to merit a true comparison. Firstly, the Examiner points to the different amounts of colloidal anhydrous silica in Formulation I (4 mg) and Formulation II (6 mg). Applicants submit that the 2 mg difference in the solution prior to spray drying is not significant in light of the additional 15 mg of colloidal anhydrous silica added to the red vine extract of Formulation II **during** the drying step. As discussed above, the addition of silica during the drying step of the red vine leaf extract unexpectedly resulted in superior storage stability properties of the resulting spray-dried powder. One skilled in the art would not expect the small difference in the amount of silica in the solution to affect the more than 7-fold increase in silica added during the drying step.

Secondly, the Examiner points to the “very large discrepancy” between the amount of crospovidone between the formulations, and “thinks that Applicants” added the disintegrant crospovidone

to the second tablet to show that colloidal anhydrous silica has an effect on hardening the tablet even in the presence of a large amount of crospovidone; however, Applicants have not themselves explained this discrepancy. Hence, the data itself is not a true comparison; it is not scientific.

The applicants disagree and note that the improved stability in a tablet having both colloidal silica and the additional disintegrant is even more unexpected as one skilled in the art would reasonably conclude that tablets having additional disintegrants would have reduced stability.

In light of the above discussion, the applicants submit the superior effects of the claimed amounts are clearly illustrated by the data, and would not be have been contemplated by the skilled artisan viewing the cited prior art references. The Examiner points to nothing else in the art that would create an expectation of success for the product of claim 1. The applicants submit the Examiner has failed to show why the claimed invention would have been obvious. Therefore, claim 1 is not obvious and is allowable. Claims 5-16 and 29-30 which depend from claim 1 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

On page 5 the Examiner rejected claims 1, 5-16 and 29-30 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Pat. No. 6,991,816 (Esperester et al., the “’816 patent”) in view of Struengmann (U.S. 6,284,269) in view of Mathowitz (1999) in view of Esperester et al. (WO 01/28363) in view of Abramovici et al. (U.S. 6,303,626) in view of Saslawski et al. (U.S. 6,426,087). The applicants respectfully traverse the rejection. For reasons similar to those discussed above, the applicants submit the superior results achieved would not be have been contemplated by the skilled artisan viewing the cited prior art references. Thus, claim 1 is not obvious over the ‘816 patent in view of Struengmann in view of Mathowitz in view of the ‘363 reference in view of Abramovici in view of Saslawski, and is therefore allowable. Claims 5-16 and 29-30 which depend from claim 1 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

Applicants submit that all claims pending in the patent application are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. The fee for a one month extension is included herewith. The applicants reiterate the finality of the instant Office Action is premature. Nevertheless, the fee for a RCE is also included herewith. Applicants request the RCE fee be refunded upon withdrawal of the finality of the Office Action. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

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Respectfully submitted,

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